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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,104

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Birkir Sveinsson

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EXAMINER

WEN, SHARON X

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

09/02/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,104	<b>Applicant(s)</b> SVEINSSON, BIRKIR	
	<b>Examiner</b> SHARON WEN	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 15, 18-20 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 15, 18-20, 23 and 25-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 03/22/2010 has been entered.

2. Applicant's amendment, filed 03/22/2010, has been entered.

Claims 4, 6-14, 16-17 and 21-22 have been canceled.

Claims 23-26 have been added.

Claims 1-3, 5, 15, 18-20 and 23-26 are pending.

Claim 24 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1-3, 5, 15, 18-20, 23 and 25-26 are currently under examination as they read on a method of treating or remedying psoriasis comprising administering a CGRP antagonist wherein the CGRP antagonist read on the elected specie, CGRP 8-37 as set forth in SEQ ID NO: 1.

3. This Action will be in response to Applicant's Arguments/Remarks, filed 03/22/2010.

The rejections of record can be found in the previous Office Action, mailed 03/20/2009.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5, 15, 18-20, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenton et al. (U.S. Patent 6,019,967, reference of record, see entire document).

Applicant's argument and Examiner's rebuttal are essentially the same as record.

In contrast to Applicant's argument that Brenton did not teach the treatment of psoriasis with a CGRP antagonist, the following is noted.

The present claims are drawn to a single method step of treating psoriasis comprising administering CGRP 8-37. Brenton et al. taught a composition comprising a CGRP antagonist, wherein the CGRP antagonist is CGRP-8-37. (see sections below)

Briefly, the present **invention features the formulation of at least one CGRP antagonist into compositions** comprising a cosmetically, pharmaceutically or dermatologically acceptable medium, for treating sensitive skin-types, and for correcting neurogenic indications. (column 3, lines 14-18)

**CGRP-8-37, an anti-CGRP antibody, is suitable for use according to this invention, for example, as a CGRP antagonist.** (column 3, lines 65-67)

Furthermore, Brenton et al. taught using the composition comprising the CGRP antagonist for treating psoriasis. (see section below)

**These compositions** constitute, in particular, cleansing, protective, treatment or care creams for the face, for the hands, for the feet, for the major anatomical folds or for the body (for example day creams, night creams, makeup-removing creams, foundation creams and sun creams), makeup products such as fluid foundations, makeup-removing milks, body milks for care or protection, after-sun products in the form of milks, lotions, gels or mousses for skin care, such as cleansing or disinfecting lotions, antisun lotions, artificial tanning lotions, compositions for the bath, deodorizing compositions containing a bactericide, aftershave products (gels or lotions), hair-removing creams, compositions to counter insect bites, pain-relief compositions, compositions for treating acne, hyperseborrheic skin or seborrheic dermatitis, and compositions **for treating certain skin diseases such as** severe pruritus, rosacea, acne, leg ulcers, **psoriasis**, pustules and vibices. (column 4, lines 27-44)

Therefore, Brenton anticipates the present claims by teaching treating psoriasis with CGRP 8-37.

Given that Brenton et al. teach a method of treating psoriasis comprising administering topically or dermally CGRP 8-37 (e.g., see Abstract and column 4, in particular, line 44), the prior art anticipates the present claims. Furthermore, given that the prior art teaches the same or nearly the same CGRP 8-37, it would inherently "lack wildtype CGRP activity and binds to CGRP receptor" because the limitation is a mere inherent property of the CGRP antagonist.

Moreover, it is noted that Brenton taught an aqueous form of the pharmaceutical composition comprising the CGRP antagonist which implies that the formulation consists essentially of the CGRP antagonist and an excipient (see column 4, paragraphs 2-3). Furthermore, the prior art taught that the formulation is to be applied topically which reads on dermally and dermal infusion.

In response to Applicant's argument that it would not have been possible for a person of ordinary skill in the art to arrive at the conclusion that psoriasis could be treated with CGRP antagonists by looking at the long list of active agents disclosed in Brenton, it is again noted that "the standard for enablement of a prior art reference for purposes of anticipation under section 102 differs from the enablement standard under 35 USC § 112" and that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." (See, *Impax Laboratories Inc.*, 81 U.S.P.Q.2d 1001, 1012, citing *Novo Nordisk Pharms., Inc v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)).

Given the clear teaching of Brenton as noted above, one of ordinary skill in the pertinent art, upon reading Brenton, would have been able to arrive at the single method step of treating psoriasis using CGRP 8-37, as claimed.

Applicant's submission of the secret discussion of the the drug development plan has been considered. However, Applicant is reminded that under 35 USC 102(b), Applicant cannot rely on evidence to antedate the prior art that was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, **more than one year** prior to the date of application for patent in the United States. Moreover, it is noted that the evidence submitted by the Applicant is not

commensurate in scope with the claimed invention because the evidence failed to mention the specific CGRP antagonist elected for examination, i.e., CGRP 8-37.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record as it applies to amended/added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brenton et al. (U.S. Patent 6,019,967, reference of record) in view of Vaishnaw et al. (US 2003/0185824 A1).

The teaching by Brenton has been discussed above.

Brenton did not teach further exposing the subject to UVB radiation. However, it would have been obvious to one of ordinary skill in the art to include the step of exposing the subject to UVB radiation for treating psoriasis because UVB radiation exposure was a well-known method for treating psoriasis as taught by Vaishnaw (see entire document, in particular, see, e.g., Abstract and claim 14).

Given that both Brenton and Vaishnaw taught treating psoriasis, it would have been obvious to one of ordinary skill in the art, upon reading the teachings, to combine the treatment for treating psoriasis.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

***Conclusion***

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/

Examiner, Art Unit 1644

August 27, 2010